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4/7/97

Food and Drug Administration
Nashville District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

297 Plus Park Boulevard
Nashville, TN 37217

Burgd 4/7/97

April 4, 1997

CERTIFIED-RETURN RECEIPT REQUESTED

Mr. J. Trent Messick
Division President
Housecall Medical Resource, Inc.
dba/Messick Homecare, Inc.
307 Hickerson Drive
Murfreesboro, TN 37129

WARNING LETTER - 97-NSV-05

Dear Mr. Messick:

During an inspection of your medical oxygen transfilling and repacking facility located at 307 Hickerson Drive, Murfreesboro, TN, on March 24 and 25, 1997, our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211), which cause your medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The inspection revealed incomplete production records, inadequate Standard Operating Procedures, employees not adequately trained in Good Manufacturing Practice Regulations, filled cylinders of gaseous medical oxygen with more than one manufacturers label, and scales used in your transfilling operation were not calibrated. There were also no batch records, documentation of purity/identity assay, labeling and lot numbers assigned for individual home cryogenic units filled at your firm.

Your medical oxygen units should meet all of the labeling requirements described in the enclosed Federal Register of March 16, 1972. The label should also bear the statement "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical

applications, Caution: Federal law prohibits dispensing without prescription." The label should also indicate whether or not it has been produced by the air-liquefaction process as required by the United States Pharmacopeia (USP XXIII).

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Until the violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action including seizure and/or injunction without further notice.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Raymond K. Hedblad

Raymond K. Hedblad
Director, Nashville District

RKH/kl

Enclosure: Federal Register dated 3/16/72

cc: Daniel J. Kohl
President & Chief Executive Officer
Housecall Medical Resources, Inc.
100 Albernathy Road
Building 400, Suite 1825
Atlanta, GA 30328

cc: V. Kelly Britton
Division Director of
Quality Improvement
307 Hickerson Drive
Murfreesboro, TN 37129

cc: Jimmie Hopper
Director, Div. of Quality and Standards
Tennessee Department of Agriculture
Ellington Agriculture Center
Melrose Station, P. O. Box 40627
Nashville, TN 37204